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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,227	12/03/2003	Nir Dotan	25681-502-P	7497

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EXAMINER	
GRUN, JAMES LESLIE	
ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
12/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/728,227	DOTAN ET AL.	
	Examiner	Art Unit	
	JAMES L. GRUN	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *05 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-15,17-30,43-54 and 56-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-15,17-30,43-54 and 56-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The amendment filed 05 September 2008 is acknowledged and has been entered. Claims 64-70 are newly added. Claims 7, 16, 31-42, and 55 have been cancelled. Claims 1-6, 8-15, 17-30, 43-54, and 56-70 remain in the case.

The terminal disclaimer filed on 05 September 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on Application Numbers 10/843,033, 11/351,185, and 11/364,964 has been reviewed and is accepted. The terminal disclaimer has been recorded.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 8-15, 17-30, 43-54, and 56-70 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 and claims dependent thereupon, the interrelationships of the steps and components of the method are not clear, e.g. it is not clear what is binding (e.g., --IgA ACCA in the sample--) or in who or what diagnosing is being accomplished (e.g., --in the subject--).

In claim 2 and claims dependent thereupon, the interrelationships of the components are not clear because it is unclear how a sample is an individual or, further, if applicant intends, as encompassed, the control being a sample from a Crohn's patient (i.e., not having a disorder other than Crohn's disease).

In claim 5 and claims dependent thereupon, the interrelationships of the steps to those of the independent claim and the diagnosis of Crohn's disease are not clear. Further, in claim 15 and claims dependent thereupon, it is not clear which of the antibodies is "said" antibody, and if, if ACCA was intended in claim 17, redundant subject matter is being claimed.

Further, in claims 20 and 21, it is not clear which of the antibodies is "said" antibody. The relationship of "identified" to "detecting" is not clear.

In claim 6, the interrelationships of the steps to those of the independent claim and the diagnosis of Crohn's disease are not clear.

In claim 11, the interrelationships of the steps to those of the independent claim and the diagnosis of Crohn's disease are not clear.

In claim 19, the interrelationships of the steps to those of the independent claim and the diagnosis of Crohn's disease are not clear.

In claim 22 and claims dependent thereupon, the interrelationships of the steps and components of the method are not clear, e.g. it is not clear what is binding (e.g., --ALCA in the sample--) or in who or what diagnosing is being accomplished (e.g., --in the subject--).

In claim 24, the interrelationships of the steps to those of the independent claim and the diagnosis of Crohn's disease are not clear.

In claim 25, the interrelationships of the steps to those of the independent claim and the diagnosis of Crohn's disease are not clear. It is believed that --anti-Glc . . . antibody-- was intended.

In claim 26 and claims dependent thereupon, the interrelationships of the steps to those of the independent claim are not clear, e.g. diagnosis already requires ALCA.

In claim 43 and claims dependent thereupon, the interrelationships of the components are not clear because it is unclear how a sample is an individual or, further, if applicant intends, as encompassed, the control being a sample from a Crohn's patient (i.e., not having a disorder other than Crohn's disease).

In claim 46 and claims dependent thereupon, the interrelationships of the steps to those of the independent claim and the diagnosis of Crohn's disease are not clear. Further, in claim 54 and claims dependent thereupon, it is not clear which of the antibodies is "said" antibody.

Further, in claims 59 and 60, it is not clear which of the antibodies is "said" antibody. The relationship of "identified" to "detecting" is not clear.

In claim 47, the interrelationships of the steps to those of the independent claim and the diagnosis of Crohn's disease are not clear.

In claim 58, the interrelationships of the steps to those of the independent claim and the diagnosis of Crohn's disease are not clear.

In claim 61, the interrelationships of the steps to those of the independent claim and the diagnosis of Crohn's disease are not clear.

Claim 62 is redundant and does not appear to limit the subject matter of claim 1.

In claim 64, it is not clear what is binding (e.g., --ASCA in the sample--) or in who or what diagnosing is being accomplished (e.g., --in the subject--).

In claim 65, it is not clear what is binding (e.g., --ALCA in the sample--) or in who or what diagnosing is being accomplished (e.g., --in the subject--). It is believed that --Glc(β1,3)Glc(β)-- was intended.

In claim 66, it is not clear what is binding (e.g., --AMCA in the sample--) or in who or what diagnosing is being accomplished (e.g., --in the subject--).

In claim 67 and claims dependent thereupon, it is not clear what is binding (e.g.: --ACCA in the sample--; --ALCA in the sample--; --ASCA in the sample--; --AMCA in the sample--).

In claim 30, the interrelationships of the steps and components of the method are not clear, e.g. it is not clear what is binding (e.g., --ALCA in the sample--). In this claim, ASCA is not defined. It is believed that --IgG anti-Glc(β1,3)Glc(β) antibody-- was intended. Improper Markush language is used to claim the members of the group. The alternatives "at least one of...or" or "at least one selected from the group consisting of...and" are acceptable.

Applicant's arguments filed 05 September 2008 have been fully considered but they are not deemed to be persuasive.

Notwithstanding applicant's assertions to the contrary, the claims remain unclear, applicant's amendments have not obviated rejections under this statute, and the claims remain rejected for the reasons set forth above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 11 a.m. to 7 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, SPE, can be contacted at (571) 272-0806.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J. L. G./
James L. Grun, Ph.D.
Examiner, Art Unit 1641
December 24, 2008

/Ann Y. Lam/
Primary Examiner, Art Unit 1641
December 21, 2008